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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,388	02/05/2004	Horst Georg Zerbe	2004-0189	3058

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EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1612

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/771,388	Applicant(s) ZERBE ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-23, 26, 27, 29, 31, 33-60 and 62-65 is/are pending in the application.
- 4a) Of the above claim(s) 41-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-23, 26, 27, 29, 31, 33-40, 52-60 and 62-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed March 1, 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The indicated allowability of claims 10-23, 57 and 58 is withdrawn in view of the newly discovered reference(s) to Miano et al. (USP 3,931,824). Rejections based on the newly cited reference(s) follow.

Claims

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29, 31, 33-40, 52-56, 59 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 37 recites the broad recitation "between 1:10 and 1:1", and the claim also recites "preferably between 1:5 and 1:3" which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejections)

1) Claims 10-20, 57 and 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miano et al. (USP 3,931,824).

Miano et al. disclose compositions that are formulated into films (col. 4, lines 42-46). The compositions comprise combustible materials such as carboxymethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, starches and the like (col. 2, lines 39-45). Generally the film will have a thickness of about 2 to about 20 mils (col. 4, lines 62-67), which encompasses 50.8 micrometers to 508 micrometers. Second combustible materials are also added and include pectins, natural gums and celluloses, which would encompass mixtures of polymers. These components comprise 0 to 40% of the compositions. (col. 5, lines 23-25). Taste modifiers include tobacco extracts, fruit extracts, flavorants, sugars and natural gums. Nicotine may also be added in controlled amounts (col. 5, lines 43-50). Coloring agents may also be added. Plasticizers are added to the films to increase flexibility and include water, glycerol and propylene glycol (col. 5, lines 63-68). Film formation may also be improved by incorporating wetting agents such as polyoxyethylene (20) sorbitan monolaurate and a polyglycol ether of trimethyl nonanol, which is considered a polyoxyethylene alkyl ether (col. 6, lines 4-8), encompassing the surfactants of the instant claims.

The reference differs from the instant claims insofar as it does not disclose an example of a film comprising each component recited in the instant claims in one composition or that the surfactants are used in mixtures.

The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such “picking and choosing” within several variables does not necessarily give rise to anticipation. Corning Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference does not provide any motivation to select this specific combination of variables (a polymer, one or more actives, one or more flavorings, one or more sweeteners and a mixture of two non-ionic surfactants), anticipation cannot be found.

That being said, however, it must be remembered that “[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious”. KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” Id. at 1742.

Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed ingredients one or more polymers, one or more actives, one or more flavorings, one or more sweeteners and a mixture of two non-ionic surfactants from within a prior art disclosure, to arrive compositions “yielding no more than one would expect from such an arrangement”.

In regard to the mixture of surfactants, generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. It would have been obvious to one of ordinary skill in the art to have combined polyoxyethylene (20) sorbitan monolaurate and polyglycol ether of trimethyl nonanol in the films of the reference to form a third surfactant used for the very same purpose as supported by MPEP 2144.06.

In regard to claims 13 and 15-17, the prior art does not disclose the exact claimed values of a film thickness of 5 to 200 micrometers, but does overlap disclosing 50.8 to 508 micrometers: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

In regards to the film exhibiting instant wettability followed by rapid dissolution, the films of the reference are made of substantially the same water soluble polymers, such as celluloses such as hydroxyalkyl cellulose, as the instant claims and therefore should have substantially the same properties because the polymers control the

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wettability and dissolution of the film. Furthermore it would take no more than routine optimization and the relative skill of one of ordinary skill in the art to determine the proportions of polymers to arrive at a film with the desired rate of water hydration and dissolution. See MPEP 2144.05 II.

2) Claims 10-21, 23, 26, 27, 57, 58 and 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeti (US 5,599,554, already of record) in view of Miano et al. (USP 3,931,824).

Majeti discloses films comprising one or more layers for the delivery of nicotine transmucosally. The compositions comprise polymers such as polyvinyl alcohol, hydroxypropyl cellulose, polyethylene oxide homopolymers, polyvinyl pyrrolidone (PVP) and mixtures thereof. The polymers may comprise 40% to 90% of the composition (col. 4, line 55 to col. 5, line 5). Plasticizers are included such as polyethylene glycol and sorbitol (col. 5, lines 45-53) and may comprise from 2% to 10% encompassing claim 35. The adhesive layer' thickness ranges from 0.1 mm to 7 mm. The concentration of nicotine varies from 1mg to 100mg (col. 4, lines 9-11) and comprises 1% and 2% of the Examples, encompassing claims 26 and 27. Aromatic oils are included in the compositions and include menthol. Other ingredients include chlorhexidine, dispersants, surfactants, humectants, pigments and colorings. Actives also include caffeine.

The reference differs from the instant claims insofar as it does not disclose all the components in one composition or the type of surfactants.

Miano et al. is discussed above and discloses surfactants are used to aid in film formation. The reference differs from the instant claims insofar as it does not disclose the specific mixture recited in the instant claims are used in the disclosed films but does disclose the surfactants individually may be used. It also does not disclose the amounts of polymer used as recited in claims 23, 26 and 27.

It would have been obvious to one of ordinary skill in the art to have used a combination of polyoxyethylene (20) sorbitan monolaurate and a polyglycol ether of trimethyl nonanol, in the films of Majeti motivated by the desire to use surfactants that aid film formation as disclosed by Miano et al.

It would have been obvious to one of ordinary skill in the art to have combined polyoxyethylene (20) sorbitan monolaurate and a polyglycol ether of trimethyl nonanol in the film of Majeti to form a third surfactant used for the very same purpose as supported by MPEP 2144.06, cited above.

In regards to the film exhibiting instant wettability followed by rapid dissolution, the films of the reference are made of substantially the same water soluble polymers, such as PVP and hydroxyalkyl cellulose, in substantially the same amounts as the instant claims and therefore should have substantially the same properties because the polymers control the wettability and dissolution of the film. Furthermore it would take no more than routine optimization and the relative skill of one of ordinary skill in the art to determine the proportions of polymers to arrive at a film with the desired rate of water

hydration and dissolution. See MPEP 2144.05 II.

3) Claims 22, 29, 31, 33, 34, 35-40 and 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeti (US 5,599,554, already of record) in view of Miano et al. (USP 3,931,824) as applied to claims 10-21, 23, 26, 27, 57, 58 and 62-65, in further view of Acharya (US 5,686,094, already of record).

Majeti and Miano et al. are discussed above and differ from the instant claims insofar as they do not disclose the compositions polymer is hydroxypropyl methyl cellulose or that tartaric acid is a flavor enhancer as recited in claim 22.

Acharya teaches polymeric delivery systems which can be used in the oral cavity and has previously been discussed in detail in the office action mailed June 16, 2006. It is disclosed using cellulose polymers control the release rate of the actives from the film matrix. Cellulose polymers include methylcellulose, hydroxypropyl methyl cellulose, hydroxypropyl cellulose, hydroxymethyl cellulose or hydroxyethyl cellulose, cellulose, gum xanthan and mixtures thereof (col. 5, lines 44-60). Other conventional ingredients, which may optionally be present, include preservatives, stabilizers, plasticizers, co-solvents, anti-adherents or silica flow conditioners as well as FD&C colors (col. 6, lines 48-61). Other ingredients that can be present in the compositions include breath fresheners and flavors, e.g., spearmint oil, peppermint oil, menthol and tartaric acid (col. 9, lines 10-15), which is a flavor enhancer.

The reference differs from the instant claims insofar as it does not teach using two surfactants in the compositions dimensions of the films.

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Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have incorporated tartaric acid as a flavor enhancer and hydroxypropyl methyl cellulose in combination with PVP as a mixture of essential components in the compositions of the combined teachings of Majeti and Miano et al. motivated by the desire to use the components for their known function as water soluble or water dispersible polymers and flavor enhancing agents. It would also have been obvious to use a mixture of polymers because it is suggested by Miano et al. and it would have been obvious for one of ordinary skill in the art to have combined hydroxypropyl methyl cellulose and PVP in the films of the combined teachings of Majeti and Miano et al. to form a third polymer system used for the very same purpose as supported by MPEP 2144.06, cited above.

4) Claims 52, 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeti (US 5,599,554, already of record) in view of Miano et al. (USP 3,931,824) and Acharya (US 5,686,094, already of record) in further view of Dam (USP 5,733,574, already of record) and Stanley (USP 5,783,207, already of record).

Majeti, Miano et al. and Acharya are discussed above and differ from the instant claims insofar as they do not disclose the compositions comprise caramel or nicotine salicylate.

Dam discloses compositions for treating nicotine addiction. The compositions are formulated into gels and comprise nicotine or their salts. The compositions comprise coloring agents such as caramel, sweeteners, flavoring and stabilizing agents such as tartaric acid. The reference differs from the instant claims insofar as it does not disclose the compositions are a monolayer films or the compositions comprising water-soluble polymers.

Stanley et al. teach dosage forms comprising nicotine and its salts. Nicotine is released from a dosage form and absorbed through the intra-oral mucosal surfaces as the nicotine-containing matrix releases nicotine within the user's mouth. Nicotine is available in either the free base or salt form. Nicotine base is readily absorbed through mucosal membranes but is highly volatile. Nicotine salts, on the other hand, are not readily absorbable through mucosal membranes but are much more stable. Pharmaceutically acceptable nicotine salts include, but are not limited to nicotine hydrochloride and nicotine salicylate. In an alkaline environment, i.e., pH above about 7, and in the presence of an aqueous medium, such as saliva within the oral cavity, nicotine salts react to form nicotine base. In addition to nicotine in a releasable form, which is readily absorbed transmucosally; the nicotine-containing compositions in accord with the present invention may contain other ingredients such as flavorings, sweeteners, flavor enhancers, lubricants, binders and fillers. The reference differs from the instant claims insofar as it does not teach the matrices as being able to rapidly disintegrate or soften immediately.

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Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have incorporated nicotine salts and caramel in the compositions of the combined teachings of Majeti, Miano et al. and Acharya motivated by the desire to use a coloring agent disclosed by the art as suitable for nicotine comprising compositions.

It would have been obvious to one of ordinary skill in the art to have used nicotine salicylate in the compositions of the combined teachings of Majeti, Miano et al. and Acharya motivated by the desire to produce a dosage form wherein the active ingredient was stable as disclosed by the Stanley.

Claims 10-23, 26, 27, 29, 31, 33-40, 52-60 and 62-65 are rejected

Claims 41-51 are withdrawn

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612